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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,226	03/25/2004	Julie Dyall	3219/7	6542

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,226	DYALL ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/10/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *12-15 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 11, 16-18, 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 10/10/2006. The status of the claims is as follows: claims 1, 11, 16-18 and 22-26 are under current examination, claims 2-10 and 27-69 are canceled and claims 12-15 and 19-21 are drawn to non-elected inventions. Applicant elected the following species: a chemical as the candidate antiviral agent and quantitation of portion of nucleic acid as the means for detection of the antiviral agent.

Please note that this application has been transferred to another Examiner and all further correspondences regarding this case should be addressed to Michelle Horning of AU 1648.

Applicant's election without traverse of a chemical and quantitation of portion of nucleic acid in the reply filed on 10/10/2006 is acknowledged.

Claim Rejections

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11, 16-18 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0034732 A1 (hereinafter as "Capon et al"). The limitations of

the rejected claims above are as follows: 1. a method of screening a candidate antiviral agent for antiviral activity comprising: a. preparing a first and a second cell culture in which the cells in each contain a first and second subgenomic viral replication system, b. adding the candidate antiviral agent to each culture; c. incubating the cultures under optimal conditions and for a sufficient amount of time to detect an antiviral effect by the agent on the viral replication systems; and d. determining the effect of the agent on each viral system, wherein the first and second subgenomic viral system is genetically distinct; 2. wherein the agent is a chemical; 3. wherein the effect of the agent is determinded by quantitation of a portion of the nucleic acid of the viral system, more specifically, by RT-PCR; 4. wherein the viral system is either stably or not stably maintained in a cell; and 5. wherein the cell culture comprises primary cells.

The limitations above are met by the teachings of Capon et al. Briefly, Capon et al discloses a method for determining the susceptibility to an HCV antiviral drug and to an HCMV antiviral drug using various resistance test vectors, including replicons and defective genomes that are derived from patients infected with HCV and HCMV and introduced them into host cells that anticipating the method instantly claimed (see Abstract). Further, this prior art reference discloses that a test vector may be delivered to the host cell at the time of infection or may be stably integrated into the target host cell chromosomal DNA (see paragraph 95). Host cells are discussed in paragraph 120 and can be derived from human tissues, including hepatocytes. Lastly, Capon et al teach that RT-PCR is a sensitive method that can be used to detect replication in *in vitro*

expression systems. Given the limitations above are taught by the prior art, these claims are rejected.

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capon et al and Olivo et al (1998, cited). The limitations of the rejected claims above are as follows: 1. a method of screening a candidate antiviral agent for antiviral activity comprising: a. preparing a first and a second cell culture in which the cells in each contain a first and second subgenomic viral replication system, b. adding the candidate antiviral agent to each culture; c. incubating the cultures under optimal conditions and for a sufficient amount of time to detect an antiviral effect by the

agent on the viral replication systems; and d. determining the effect of the agent on each viral system, wherein the first and second subgenomic viral system is genetically distinct; 2. wherein the cell cultures are incubated at least 20 hours; 3. wherein the method further comprises a third cell culture with cells containing a third subgenomic viral replication system distinct from the first and second viral systems.

As discussed above, limitation #1 above is met by the teachings of Cabon et al. Capon et al does not teach incubation of the cell culture with the antiviral agent for 20 hours or more or using a third cell culture with a third subgenomic viral replication system distinct from the first and second viral systems. It would have been obvious for one of ordinary skill in the art to incubate the cell cultures with a candidate antiviral agent at varying durations. One would have been motivated to do so in order to determine what the optimal incubation times would be for differential drugs in producing an antiviral effect and in characterizing these effects. It would have been obvious for the ordinary artisan to further screen for antiviral effects of a single drug on multiple cell cultures containing each containing a distinct subgenomic viral replication system. One would have been motivated to do so in order to efficiently determine the antiviral activity of a single drug for multiple subgenomic viral replication systems at once. The expectation of success would have been reasonable in determining optimal incubation times and multiple target screening of a single drug, given the techniques are well described and commonly used by the ordinary artisan. Furthermore, Olivo et al recites the following regarding the requirements of this method in preparing a single cell culture: "the preparation of the cells requires two separate steps (electroporation of the

replicon followed by puromycin selection and plasmid transfection), but once the cells are prepared, the protocols for virus inoculation, sample processing, and data readout are quite simple" (see page 20). Olivo et al suggest that this approach could be used in screening antiviral drugs and in evaluating the efficacy of vaccines. Also, this approach may successfully apply to many different viruses by incorporating virus-specific *cis* and *trans*-acting factors into the assay (page 20). Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

CONCLUSIONS

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michelle Horning
Patent Examiner

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